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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/187,661	11/05/98	SHIRLEY	B 5784-3

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INTELLECTUAL PROPERTY-R440
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EXAMINER

MOEZIE, F

ART UNIT	PAPER NUMBER
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1653

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DATE MAILED: 04/21/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/187,661

Applicant(s)
Shirley et al

Examiner
F. T. Moezie

Group Art Unit
1653



☒ Responsive to communication(s) filed on 11/06/99, 07/12/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-27 is/are pending in the application.

Of the above, claim(s) 5-7, 9-11, 14, 15, and 21-27 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4, 8, 12, 13, and 16-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-27 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 1/3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

STATUS OF CLAIMS

Claims 1-4, 8, 12, 13 and 16-20 are pending prosecution in this Office action.

SPECIFICATION - OBJECTION

The specification is objected to because there are blank spaces in various parts of the specification. See, for example, pages 2, 8 and 14, lines 2, 6 and 29, respectively.

REJECTIONS - 35 USC 112, FIRST AND SECOND PARAGRAPHS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8, 12, 13 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is a lack of description for using "variants " of IGF-I in the specification as filed. Furthermore, there is a lack of description for claims 16-20 subject matter.

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Claims 1-4, 8, 12, 13, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The use for "variants" of IGF-I has not been shown. The polypeptide, IGF-1 contains chemically reactive functional groups and require proper secondary and tertiary structure to be active. The "variants" of IGF-I require chemical modification of the molecule and such modification can lead to loss of activity or increased immunogenicity thereby limiting the efficacy for the "variant" in the practice of the invention. See the article by Johnson et al, at page 795, submitted by applicant.

Claims 1, 4, 8, 13 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The "low salt concentration" which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See for example, see page 2, and 4, lines 18 and 11, respectively. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-4, 8, 12, 13 and 16-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "variant thereof" render the claims indefinite as to the claims metes and bounds.

In claims 1-4, 8, 12, 13 and 16-20 the terms "highly concentrated " and "low salt " render the claims indefinite as to the claims metes and bounds.

Claims 1, 8 and 12 are indefinite and duplicative of one another, being drawn to substantially the same composition of matter.

In claims 16-20 the term "container means" render the claims indefinite as to what is intended and the claims metes and bounds.

In claims 2-4 the terminology "a low salt containing", fails to find antecedent basis in claim 1, from which they depend.

Claims 1-4, 8, 12, 13 are improper composition claims as they are drawn to a compound.

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CLAIMS OBJECTION

Claims 16-20 are objected to because they depend from a non-elected claim, claim 15.

REJECTION - 35 USC 103 (a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-4, 8, 12, 13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al, in NATURE MEDICINE, volume 2, no. 7, pages 795-799, July 1996.

The reference discloses a sustained-release form of hGH complex - complexed with zinc salt - wherein the protein was prepared in microspheres using a novel cryogenic process (abstract). The reference teaches that "possibly other proteins, when delivered in a continuous fashion that maintains its concentration within the therapeutic window" page 798, first column. See the entire document.

An ordinary art skilled at the time the invention was made would have expected that following the teachings of the reference using IGF-I would result in a formulation as claimed.

RESPONSE TO THE RESTRICTION REQUIREMENT

The response filed 12 July 1999 has been entered.

Applicant elected Group I invention, claims 1-4,8, 12, 13 and 16-20, with traverse. However, because applicant did not present any reason(s) for the traversal of the requirement, the election is treated as having been made without traverse.

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The restriction requirement is made Final.

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication should be directed to F. T.
Moezie at telephone number (703) 305-4508 or Mr. LOW (SPE) at 308-
2923. FAX: (703) 305-7401

F. T. Moezie
F. T. MOEZIE, P.E.
PRIMARY EXAMINER
ART UNIT ~~4~~
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